

PSJ11 CVS Opp Exh 22

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

HOLIDAY CVS, L.L.C.,
d/b/a CVS/Pharmacy Nos. 5195/219

Plaintiff,

v.

ERIC HOLDER, JR., *et al.*,

Defendant.

Civ. No. 1:12-cv-191

DECLARATION OF JOSEPH RANNAZZISI

I, Joseph Rannazzisi, pursuant to 28 U.S.C. § 1746, declare and state as follows:

1. I am currently the Deputy Assistant Administrator for DEA's Office of Diversion Control. In that capacity I coordinate the day-to-day operations of the Diversion Control Program; brief representatives from the pharmaceutical industry, members of Congress, executive staff at the Department of Justice and the Office of National Drug Control Policy, as well as the general public on the national epidemic of prescription drug abuse and the diversion of controlled substance pharmaceuticals.
2. I am a Special Agent of the United States Department of Justice, Drug Enforcement Administration (DEA) and have been employed by the DEA since 1986. Additionally, I have a Bachelor of Science Degree in Pharmacy and am a licensed pharmacist. I also hold a Juris Doctorate from the Detroit College of Law at Michigan State University.

3. Matters contained in this declaration are based upon my personal knowledge, training, experience, and upon conclusions and determinations reached by me. I participated in the decision-making process that led to the issuance of an Immediate Suspension Orders (ISOs) against Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #219 (CVS 219) and CVS/Pharmacy #5195 (CVS 5195) (collectively, "CVS") on February 2, 2012. The contents of the declaration, including history, facts, conclusions, and determinations, were before DEA prior to the issuance of the ISOs against CVS 219 and CVS 5195.

Regulatory Scheme

4. The Food and Drug Administration generally regulates pharmaceutical drugs. Congress, however, recognized the need for greater scrutiny over controlled substances, due to their potential for abuse and danger to public health and safety. As such, it established a separate framework under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, and implementing regulations, that creates a closed system of distribution for all controlled substances and listed chemicals. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
5. Congress therefore established a comprehensive regulatory scheme in which controlled substances are placed in one of five "Schedules" depending on their potential for abuse, the extent to which they may lead to psychological or physical dependence, and whether they have a currently accepted medical use in treatment in the United States. *See* 21 U.S.C. § 812(b). Controlled substances in "Schedule I" have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and a "lack of accepted safety for use under medical supervision."

21 U.S.C. § 812(b)(1)(A)-(C). Controlled substances in Schedule II do have “a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, but still have “a high potential for abuse.” “Abuse of the drug or other substances may lead to severe psychological or physical dependence.” 21 U.S.C. § 812(b)(2)(A)-(C).

6. The CSA gives the Drug Enforcement Administration broad authority to prevent the diversion of pharmaceutical drugs for illicit use. *See* 21 U.S.C. §§ 824(d), 871(a); 21 C.F.R. §§ 1316.65(c) and 1316.67; 28 C.F.R. § 0.104, Appendix to Subpart R, Sec. 7(a). “Diversion” is a term used to describe instances when licit drugs leave the closed-system of distribution for illicit purposes.
7. As part of that authority, the DEA Office of Diversion Control regulates every link in the prescription-drug supply chain and is responsible for regulating more than 1.4 million DEA registrants. Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration with DEA. 21 C.F.R. § 1301.11. It is the responsibility of the Office of Diversion Control to ensure that these registrants adhere to all aspects of the CSA and implementing regulations and to take action against them when they are out of compliance.
8. The closed system of the CSA is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system.

9. Specifically, with respect to pharmacies, registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 C.F.R. § 1306.04(a). Pharmacists are required to ensure that prescriptions for controlled substances are “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a).
10. When registrants at every level—practitioners, pharmacies and distributors—fail to fulfill their obligations, these necessary checks and balances collapse. Because pharmacies are the entity providing the controlled substances to the end user, they are often the last major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. It is, therefore, incumbent on pharmacies to ensure that controlled substances are only dispensed pursuant to valid prescriptions issued for legitimate medical purposes in the usual course of professional practice.
11. When a pharmacy is not adhering to its legal obligations, the DEA has authority to revoke or suspend its registration. *See* 21 U.S.C. § 823(f) (describing that issuance of a practitioner’s registration (including pharmacies) must be consistent with the public interest, as determined by the following five factors: (1) the recommendation of the appropriate State licensing board or professional disciplinary authority; (2) the applicant’s experience in dispensing, or conducting research with respect to

controlled substances; (3) the applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances; (4) compliance with applicable State, Federal, or local laws relating to controlled substances; and (5) such other conduct which may threaten the public health and safety). Ordinarily, DEA must hold a hearing prior to revocation or suspension of an entity's registration. But when the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," DEA has discretion to suspend that party's registration immediately, prior to an administrative hearing. 21 U.S.C. § 824(d). DEA must provide the basis for its suspension in an Order to Show Cause. 21 C.F.R. § 1301.36(e). A Section 824(d) suspension remains in effect until the DEA issues a final order, unless the suspension is withdrawn by the Attorney General or dissolved by a court of competent jurisdiction. 21 U.S.C. § 824(d). A Section 824(d) suspension only suspends a registrant's ability to handle controlled substances and does not affect the registrant's ability to handle non-controlled pharmaceutical drugs.

The Rampant Problem of Controlled Substance Diversion for Illicit Use

12. Prescription drug abuse occurs in the United States at an alarming rate. The 2010 National Survey on Drug Use and Health reveals that approximately 7 million Americans abuse controlled substance pharmaceuticals for non-medical purposes. See 2010 National Survey on Drug Use and Health Survey, (2010 Survey) available at <http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.pdf>. Second only to marijuana, controlled substance prescription drugs are abused by more people than cocaine, heroin, hallucinogens and inhalants combined.

13. Of all prescription drugs, narcotic pain relievers such as oxycodone, hydrocodone, and oxymorphone are abused most frequently. Each year, roughly 5.1 million people abuse narcotic pain relievers in the United States. Oxycodone is a Schedule II controlled substance. *See* 21 C.F.R. § 1308.12(b)(1)(xiii).
14. Over the past several years, DEA has seen two major schemes used to divert powerful and addictive controlled substance pharmaceuticals. First, between 2005 and 2009, hydrocodone, a Schedule III controlled substance, was illegally diverted through rogue Internet pharmacy schemes. Florida was the epicenter for many of the illegal operations whereby tens of millions of dosage units of hydrocodone were diverted to locations across the United States. For reference, a dosage unit is most commonly applied to a tablet. It is the main ingredient, expressed in milligrams or milliliters (liquids), in combination with other ingredients, binders and fillers. Congress reacted to the plethora of rogue Internet pharmacies with the passage of the Ryan Haight Online Pharmacy Consumer Protection Act that took effect in April 2009. This action along with intensified law enforcement actions virtually eliminated domestic-based rogue Internet pharmacies.
15. Second, beginning in late 2008 and continuing to the present, there has been a significant rise in the number of rogue pain clinics whose complicit doctors initially dispensed millions of dosage units of oxycodone, a Schedule II controlled substance more potent than the hydrocodone that was previously dispensed through the rogue Internet operations. Again, Florida was and remains the epicenter for these illegal pain clinics. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based pain clinics to obtain their

supply of oxycodone, and other controlled substances such as alprazolam, which is in turn illegally redistributed in states along the entire east coast and Midwest.

16. Florida has attempted to address this problem through a patchwork of legislation.

Some of the more current state legislation has placed a restriction on a physician's ability to dispense oxycodone from the clinic. The illicit pain clinics responded by issuing prescriptions for oxycodone rather than dispensing directly to the drug seeker.

17. According to the Florida Medical Examiner's Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just five drugs: methadone, oxycodone, hydrocodone, benzodiazepines, or morphine. This is an average of 11.2 persons dying in the state of Florida every day from just these five drugs alone.

18. Furthermore, the abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as the "trinity" or "holy trinity," hydrocodone or oxycodone used in combination with alprazolam (a benzodiazepine) and carisoprodol. According to the Florida Medical Examiner's Office, they have seen a 127% increase in the number of deaths associated with benzodiazepines in the State of Florida between 2005 and 2010.

19. Florida has tried to rein in prescription-drug abuse by enacting laws that limit Florida physicians' ability to dispense controlled substances. Until 2010, FLA. STAT. § 465.0276 allowed a practitioner to dispense drugs in the usual course of professional

practice so long as s/he was registered as such and paid a \$100 fee. The practitioner was subject to the same record-keeping requirements and periodic inspections as a pharmacy. In 2010, the Florida legislature amended FLA. STAT. § 465.0276 to prohibit a registered practitioner from dispensing more than a 72-hour supply of any controlled substance for any patient who paid for the medication with cash, check or credit card. The law became effective October 1, 2010. Finally, in 2011, the Florida legislature amended the statute a second time to prohibit a practitioner, except in very limited circumstances, from dispensing any controlled substances in Schedules II and III. The law became effective July 1, 2011.

20. On July 1, 2011, the State Health Officer and Surgeon General, Dr. Frank Farmer issued a statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida, titled "State Surgeon General Declares Public Health Emergency Regarding Prescription Drug Abuse Epidemic." The press release noted that "In 2010, 98 of the top 100 doctors dispensing Oxycodone nationally were in Florida," that "In 2010, 126 million Oxycodone pills were dispensed through the top 100 dispensing pharmacies in Florida," "More Oxycodone is dispensed in the state of Florida than in the remaining states combined." Attachment 1.
21. The changes in the law have changed the way drug abusers obtain oxycodone. Rather than dispensing the drug directly to "patients," pain clinics and complicit doctors now write prescriptions for oxycodone. Drug abusers wanting their prescriptions filled must take their script to retail pharmacies like CVS 219 and CVS 5195.

22. Following these changes in the law, law enforcement saw immediate and significant increases in the volume of oxycodone dispensed from retail pharmacies across the state of Florida.
23. The doctors and clinics that prescribe oxycodone inappropriately, the pharmacies that dispense their prescriptions, including CVS 219 and CVS 5195, have caused, and continue to cause, millions of dosage units of oxycodone to be diverted for unlawful use thereby creating an imminent threat to the public health and safety.

CVS 219 and CVS 5195

24. CVS 219, located at 3798 Orlando Drive, Sanford, Florida 32773 is registered with the DEA as a chain pharmacy in Schedules II, III, IV and V controlled substances under DEA Registration Number BC5289055. DEA Registration Number BC5289055 expires by its terms on December 31, 2013. Attachment 2.
25. CVS 5195, located at 4639 W. 1st Street, Sanford, Florida 32771 is registered with the DEA as a chain pharmacy in Schedules II, III, IV and V controlled substances under DEA Registration Number BC6988298. DEA Registration Number BC6988298 expires by its terms on December 31, 2013. Attachment 3.

Notice to CVS of Diversion Problem

26. On December 8, 2010, DEA hosted a meeting with CVS at the DEA West Palm Beach Resident Office. In attendance at the meeting were representatives from DEA, the Florida Department of Health (DOH) and CVS (including counsel for CVS/Caremark, Inc. and the district supervisor for CVS 219 and CVS 5195). Specifically, the following individuals were present:
- a. Group Supervisor Susan Langston, DEA
 - b. Group Supervisor Gayle Lane, DEA

- c. Diversion Investigator Phyllis Garret, DEA
- d. Supervisor Michelle Miller, DOH
- e. Senior Pharmacist Robert DiFiore, DOH
- f. John Gilbert, Counsel for CVS/Caremark
- g. District Supervisor, Jennifer Lalani, RPh, CVS
- h. District Supervisor, Papatya Tankut, RPh, CVS

27. The meeting commenced with a brief statement by John Gilbert, counsel for CVS/Caremark, Inc. Mr. Gilbert stated that CVS was aware of the pill mill and/or pain clinic situation and the diversion of controlled substances, primarily oxycodone, in Florida. Mr. Gilbert further stated that CVS was seeking additional guidance from DEA to better understand the diversion issue(s) in Florida.

28. DEA and DOH advised CVS that the diversion of oxycodone, primarily originating from purported pain clinics, involves fraudulent prescriptions, doctor shoppers, and unethical doctors. CVS was further advised of the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam); (b) many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain); and (e) individuals driving long distances to visit physicians and/or to fill prescriptions.

29. CVS 219's and CVS 5195's District Supervisor, Jennifer Lalani, acknowledged that she was aware of an increase in the number of oxycodone prescriptions that have been presented to CVS pharmacies, especially in the Orlando, Florida area. Ms. Lalani also made reference to an October 2010 letter sent to pharmacies from Hillsborough County Sheriff David Gee. In that letter, Sheriff Gee made a plea to area pharmacies to work with law enforcement and closely scrutinize the prescriptions they receive in order to deal with the prescription drug epidemic in Florida. Attachment 4.
30. Ms. Lalani stated that CVS pharmacists had been instructed to verify oxycodone prescriptions by calling the prescribing practitioner. DEA informed the CVS representatives that verifying that the prescription was written by a physician was not the same as making an independent determination that the prescription was written for a legitimate medical purpose in the usual course of professional practice.
31. During the meeting, DEA provided the CVS representatives with a one-page summary of the oxycodone purchases made by CVS 219. Attachment 5. This information was contained within a summary from DEA's Automation of Reports and Consolidated Orders System (ARCOS) records that track the purchases of narcotic controlled substances between DEA registrants. The summary showed a huge increase in oxycodone purchases by CVS 219 from 2006 through 2010. Specifically, the pharmacy ordered approximately 265,000 dosage units of oxycodone in 2006. DEA informed the CVS representatives that this amount represented more than four times the amount of oxycodone a typical pharmacy orders in one year. Additionally, through October 2010, CVS 219 ordered more than 1.8 million dosage

units of oxycodone. DEA informed the CVS representatives that this 10 month order history represented more than thirty times what a typical pharmacy ordered in one year.

32. Ms. Lalani confirmed that CVS 219 was located in Sanford, Florida and was under her supervision. Ms. Lalani agreed that the volume of oxycodone purchased by this pharmacy was extremely high; however, Ms. Lalani was unable to explain why the volume was so high. Ms. Lalani further stated that she would look into the matter.
33. On August 12, 2011, DEA hosted a second meeting with CVS at the DEA Weston Resident Office. In attendance at the meeting were DEA representatives and 24 supervisors/managers from various South Florida CVS pharmacies. Attachment 6. Jennifer Lalani was again present at this meeting. Ms. Lalani stated that she wanted to attend the meeting even though she did not supervise South Florida CVS pharmacies.
34. The meeting commenced with a brief power point presentation by DEA. Attachment 7. The presentation included statistical information from DEA, Florida Department of Law Enforcement, Center for Disease Control, and the United States Census Bureau. This information showed drastic increases in prescription drug overdose deaths. It also showed that during 2010, Florida pharmacies purchased far more oxycodone than pharmacies in any other state. DEA informed the CVS representatives that the average U.S. pharmacy purchased approximately 69,500 dosage units of oxycodone in 2010, and that the average Florida pharmacy purchased approximately 134,000 dosage units of oxycodone in 2010.

35. DEA explained to the CVS representatives that, pursuant to 21 C.F.R. § 1306.04(a), a prescription for controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice, and that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but that a corresponding responsibility rests with the pharmacist who fills the prescription.
36. CVS was again advised of the typical “red flags” associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the “red flags” discussed included: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; (e) individuals driving long distances to visit physicians and/or to fill prescriptions; (f) customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and (g) customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).
37. DEA provided the CVS representatives with a list of the top 34 CVS pharmacies in Florida for purchasing oxycodone in 2010. Attachment 8. CVS 219 ranked first on this list and CVS 5195 ranked second. Ms. Lalani acknowledged that CVS 219 and CVS 5195 were under her supervision. Ms. Lalani stated that she knew CVS 219 and CVS 5195 were two of the busiest CVS pharmacies in the state, and attributed this to

the fact that the pharmacies were open 24 hours a day and were located off of Interstate-4.

DEA Investigation of CVS 219 and CVS 5195

38. DEA's investigations of CVS 219 and CVS 5195 stemmed from DEA's investigation of the pharmacies' main distributor, which was Cardinal Health, Inc.'s Lakeland, Florida branch (Cardinal). DEA's investigation of Cardinal revealed that from January 1, 2008 through October 31, 2011, Cardinal sold over 12.8 million dosage units to its top four customers. From 2008 to 2009, Cardinal's oxycodone sales to its top four retail pharmacy customers increased approximately 803%, and from 2009 to 2010, Cardinal's oxycodone sales increased approximately 162%. Attachment 9. Between 2009-2011, Cardinal's oxycodone sales to its top four retail pharmacies increased 241%. CVS 219 and CVS 5195 were two of Cardinal's top four retail pharmacy customers during this time period.
39. Compared to the average number of dosage units distributed monthly to Cardinal's other Florida retail pharmacies, the average monthly distribution at CVS 219 and CVS 5195 was staggering. Cardinal's other Florida retail pharmacies received, on average, 5,364 dosage units per month from October 1, 2008 through December 31, 2011. Attachment 10. In contrast, CVS 5195 purchased approximately 58,223 dosage units per month and CVS 219 purchased 137,994 dosage units per month during this same period. Attachment 9.
40. On October 18, 2011, based on DEA's evaluation of ARCOS data indicating that CVS 219 and CVS 5195 were purchasing high volumes of oxycodone from Cardinal,

DEA executed Administrative Inspection Warrants ("AIWs") at CVS 219 and CVS 5195.

41. During the execution of the AIWs and thereafter, DEA personnel interviewed employees for both CVS 219 and CVS 5195. These interviews revealed the following:

- a. The Pharmacist in Charge (PIC) at CVS 219, Paras Priyadarshi, stated that the majority of the diagnosis codes listed by the prescribing practitioners on the oxycodone prescriptions were the same, and that customers requested certain brands of oxycodone, referring to them as "Ms" or "blues."¹ PIC Priyadarshi stated that he did not see anything wrong with two individuals living at the same address receiving the same exact prescriptions for oxycodone, alprazolam and muscle relaxants from the same practitioner. PIC Priyadarshi stated that no one from CVS/Caremark, Inc. had said anything to him regarding the large amounts of oxycodone purchased by CVS 219 or the prescriptions for oxycodone being filled by CVS 219.
- b. One of the pharmacists (RPh) at CVS 219, Susan Masso, stated that many of the patients receiving oxycodone prescriptions received the same "cocktail" of prescriptions, including: oxycodone 30mg, oxycodone 15mg, alprazolam 2mg and carisoprodol. RPh Masso went on to say that she was not a "police officer and [could] not police the patients." RPh Masso stated that some customers asked for their oxycodone prescriptions to be filled using "blues."
- c. The Pharmacist in Charge (PIC) at CVS 5195, Jessica Merrill, stated that she set a daily limit of how many oxycodone 30mg prescriptions the pharmacy would fill each day. The limit was set based upon the amount of oxycodone the pharmacy had on-hand each day. PIC Merrill said that the reason she set this daily limit was to ensure that the pharmacy had enough oxycodone 30mg to fill the prescriptions for "real pain patients." PIC Merrill stated that she noticed that patients brought in the same combination of controlled substance prescriptions, and that many of the oxycodone prescriptions were written for similar quantities. PIC Merrill stated that many patients paid for their oxycodone prescriptions with cash or a discount card. She also recalled instances where a vehicle would pull up to the pharmacy's drive through window with multiple people in the car, and two or more individuals in the vehicle would present prescriptions for the same controlled substances at the same quantities, on prescriptions written by the same practitioner. PIC Merrill admitted that these

¹ "Ms" or "blues" are street slang terms used to describe Mallinckrodt brand oxycodone tablets.

prescriptions probably were not legitimate and further described the pharmacy's oxycodone customers as "shady."

- d. The Store Manager at CVS 5195, Shawn Porter, stated that one of his job duties was to act as the "bouncer" for the store. Mr. Porter elaborated on this point by stating that sometimes he had to escort customers off the premises because the customers became belligerent after the pharmacy refused to fill their prescriptions for controlled substances. Mr. Porter described these particular customers as being "hooked."
- e. The Lead Pharmacy Technician (PT) at CVS 5195, Mari Morrell, stated that CVS 5195 had experienced an increase in its sales of oxycodone. PT Morrell also stated that CVS 5195's customers knew about the store's policy to only fill a certain number of oxycodone prescriptions per day, and that the prescriptions for oxycodone were filled on a "first come first served" basis. PT Morrell said that customers would arrive at the pharmacy very early each day in order to ensure their prescriptions for oxycodone could be filled. PT Morrell went on to say that the daily limit for oxycodone 30mg prescriptions was usually reached sometime between 10:00 a.m. and 12:00 p.m. each day, but that sometimes the daily limit was reached within thirty minutes of the pharmacy opening. PT Morrell also stated that it was not her job to "police the patients."
- f. One of the pharmacists (RPh) at CVS 5195, Mark Mascitelli, stated that CVS 5195 "could fill oxycodone prescriptions all day." He stated that due to the limited number of oxycodone prescriptions the pharmacy would fill each day, customers would start lining up outside the store at around 7:45 a.m. RPh Mascitelli sometimes had to ask these customers to disperse and return when the pharmacy opened at 8:00 a.m. RPh Mascitelli said that the daily limit for oxycodone prescriptions was usually reached within one half-hour to a couple of hours of the pharmacy opening each day. RPh Mascitelli went on to say that some customers asked for their oxycodone prescriptions to be filled using "Ms" or "Vs."²

42. CVS 219 and CVS 5195 continue to employ PIC Priyadarshi and PIC Merrill.

43. During the execution of the AIW and thereafter, DEA investigators reviewed CVS 219's and CVS 5195's controlled substances prescription records and found that, since at least 2010, both pharmacies filled prescriptions for controlled substances based on prescriptions issued by practitioners who have been the subject of action by DEA or the State of Florida. DEA and the State of Florida have taken criminal, civil

² "Vs" is the street slang terms used to describe the Qualitest brand oxycodone tablets.

or administrative action against at least twenty physicians, whose customers fill their controlled substance prescriptions at CVS 219 and CVS 5195, for activities resulting in the diversion of controlled substances, including for inappropriately prescribing excessive and inappropriate quantities of controlled substances and issuing prescriptions not for a legitimate medical purpose or outside the usual course of professional practice. These actions resulted in the loss of authority of these practitioners to handle controlled substances. Many of these practitioners subsequently voluntarily surrendered their DEA registrations for cause, based on their failure to comply with the Controlled Substances Act and DEA regulations.

The practitioners include the following:

- a. Carlos A. Almonte, M.D.: DEA Immediate Suspension Order dated February 18, 2011; voluntarily surrendered registration for cause on February 23, 2011;
- b. Stephen Anthony, M.D.: voluntarily surrendered registration for cause on March 24, 2011;
- c. Mladen Antolic, M.D.: DEA Order to Show Cause dated August 8, 2011; Final Order dated January 25, 2012;
- d. Anthony Attala, M.D.: voluntarily surrendered registration for cause on March 21, 2011;
- e. Lynn E. Averill, M.D.: DEA Immediate Suspension Order dated March 9, 2011; registration retired on August 1, 2011;
- f. Scott Becker, M.D.: DEA Immediate Suspension Orders dated February 18, 2011 and March 4, 2011; voluntarily surrendered registrations for cause on May 13, 2011;
- g. Bernard Cantor, M.D.: voluntarily surrendered registrations for cause on May 10, 2011;
- h. John Christensen, M.D.: voluntarily surrendered registration for cause on September 4, 2011;

- i. Jack A. Danton, M.D.: DEA Immediate Suspension Order dated November 19, 2010; Final Order dated September 30, 2011;
- j. Manuel J. Fernandez, M.D.: DEA Immediate Suspension Order dated December 14, 2010; voluntarily surrendered registration for cause December 15, 2010;
- k. David Glickman, M.D.: Florida Order of Emergency Restriction of License dated August 19, 2010; Final Order dated March 14, 2011;
- l. Paul D. Glusman, M.D.: voluntarily surrendered registration for cause on February 7, 2011;
- m. Carlos Gonzalez, M.D.: DEA Immediate Suspension Order dated February 18, 2011; voluntarily surrendered registration for cause on September 30, 2011; Final Order dated October 11, 2011;
- n. Riyaz A. Jummani, M.D.: Florida Order of Emergency Restriction of License dated June 2, 2011;
- o. John T. Legowik, M.D.: DEA Immediate Suspension Order dated November 4, 2011; voluntarily surrendered registration for cause on November 4, 2011;
- p. Ronald Lynch, M.D.: DEA Order to Show Cause dated April 4, 2008; Final Order dated January 1, 2011;
- q. Charles Neuringer, M.D.: DEA Immediate Suspension Order dated December 15, 2010; voluntarily surrendered registration for cause on December 17, 2010;
- r. Angelo V. Pace, M.D.: DEA Immediate Suspension Order dated February 15, 2011; voluntarily surrendered registration for cause on February 23, 2011;
- s. Ataur Rahman, M.D.: voluntarily surrendered registration for cause on September 28, 2010;
- t. Nader H. Shehata, M.D.: DEA Immediate Suspension Order dated March 4, 2011; voluntarily surrendered registration for cause on April 27, 2011; and
- u. Randall L. Wolff, M.D.: DEA Immediate Suspension Order dated December 14, 2010; Final Order dated February 1, 2012.

None of these practitioners were located in Sanford, Florida, where CVS 219 and CVS 5195 were located. In fact, all but four of the above listed practitioners were located in South Florida, which is generally about 200 miles from Sanford, Florida. Accordingly, customers filling the prescriptions for controlled substances issued by these South Florida practitioners at CVS 219 and CVS 5195 had to travel lengthy distances in order to obtain their controlled substances. The investigation of these practitioners and the results of those investigations illustrated the fact that CVS did not have adequate measures in place—or at least none that were actually practiced by the employees at CVS 219 and 5195—to fulfill their corresponding responsibility to ensure that these prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

44. DEA's investigations of CVS 219 and CVS 5195 also included a review and analysis of ARCOS records showing CVS 219's and CVS 5195's purchases of controlled substances. This review and analysis revealed that:

- a. From January 1, 2008 through December 31, 2011, CVS 219 purchased over 5.8 million dosage units of oxycodone products from its distributors, primarily from Cardinal. Attachment 11.
- b. From January 1, 2008 through December 31, 2011, CVS 5195 purchased over 2.2 million dosage units of oxycodone products from Cardinal. Attachment 12.
- c. From January 1, 2010 through December 31, 2011, CVS 219 purchased, on average, approximately 160,000 dosage units of oxycodone per month. During this same time period, CVS 5195 purchased, on average, approximately 87,000 dosage units of oxycodone per month. Attachments 13 and 14.
- d. From 2008 to 2009, CVS 219 increased the amount of oxycodone it purchased by approximately 75%, from 719,400 dosage units of oxycodone in 2008 to 1.25 million dosage units of oxycodone in 2009. Attachments 11 and 15. During this same time period, CVS 5195

increased the amount of oxycodone it purchased by 56%, from 66,900 dosage units of oxycodone in 2008 to 104,500 dosage units of oxycodone in 2009. Attachments 12 and 15.

- e. In 2010, CVS 219 purchased over 2 million dosage units of oxycodone, an approximately 63% increase over 2009. Attachments 11 and 15. In 2010, CVS 5195 purchased 885,900 dosage units of oxycodone, a 748% increase over 2009. Attachments 12 and 15. In comparison, the average Florida pharmacy purchased approximately 135,000 dosage units of oxycodone during the entirety of 2010. Attachment 16.
- f. In 2011, CVS 219 purchased over 1.8 million dosage units of oxycodone and CVS 5195 purchased over 1.2 million dosage units of oxycodone. Attachments 11 and 12. In comparison, the average Florida pharmacy purchased approximately 111,000 dosage units of oxycodone during the entirety of 2011. Attachment 25.
- g. Between October 2011 and December 2011, CVS 219's purchases of oxycodone decreased by 77% (from 159,000 dosage units to 37,300 dosage units). During this same time period, CVS 5195's purchases of oxycodone decreased by 84% (from 63,000 dosage units to 9,900 dosage units). Attachment 14. Despite the reduction, however, CVS 219's and CVS 5195's monthly purchases of oxycodone remained higher than that of the average Florida pharmacy, which was 7,831 dosage units between October 2011 and December 2011. Attachment 14.

45. On October 19, 2011, DEA requested from CVS 219 and CVS 5195 the controlled substance dispensing profiles for twenty-two practitioners. Attachment 17.³

Approximately one month later, CVS/Caremark, Inc. informed DEA that it was suspending the dispensing of any Schedule II narcotic prescriptions issued by these same twenty-two practitioners for a period of sixty days.⁴ Attachment 18.⁵

46. On October 20, 2011, CVS/Caremark, Inc. provided DEA with a copy of its policies regarding filling prescriptions for controlled substances. Attachment 19. These

³ Attachment 18 reflects that this request was made for twenty-four practitioners; however, two of the practitioners on the list of names provided to CVS 219 and CVS 5195 were duplicates. These names have been redacted to protect the personally identifying information of the practitioners.

⁴ The twenty-two practitioners for whom DEA was requesting the controlled substance dispensing profiles were not the same practitioners listed in paragraph 43, *supra*.

⁵ The names of the individual practitioners have been redacted.

“Dispensing Guidelines for Pain Management” provided a list of warning signs to assist CVS employees in identifying “inappropriate prescription-seeking behavior.”

47. On December 23, 2011, CVS/Caremark, Inc. provided DEA with another copy of its policies regarding filling prescriptions for controlled substances, as well as excerpts from various trainings, guides, and memoranda regarding filling prescriptions for controlled substances. Attachment 20.
48. On January 27, 2012, CVS/Caremark, Inc. provided DEA with a copy of its revised dispensing guidelines for prescriptions for controlled substances. Attachment 21.
49. A comparison of CVS/Caremark, Inc.’s revised dispensing guidelines with their previous guidelines and trainings revealed that the revised guidelines were largely the same as CVS/Caremark, Inc.’s previous policies. Further, given that employees at CVS 219 and CVS 5195 failed to follow CVS/Caremark, Inc.’s previous policies, the implementation of the revised dispensing guidelines was granted little weight.

Results of CVS 219 and CVS 5195 Investigations

Staggeringly High-Volume Purchases:

50. CVS 219 and CVS 5195 are located in Sanford, Florida. During 2011, CVS 219 purchased over 1.8 million dosage units of oxycodone and CVS 5195 purchased over 1.2 million dosage units of oxycodone. According to the 2010 U.S. Census Bureau Facts Sheet, Sanford, Florida has a population of 53,570. Attachment 22. Based on these numbers, CVS 219’s and CVS 5195’s dispensing of oxycodone could supply every resident of Sanford, Florida with approximately 56 dosage units of oxycodone.

51. In 2011, CVS 219 purchased 1,802,100 dosage units of oxycodone and CVS 5195 purchased 1,210,400 dosage units of oxycodone. This volume dwarfs the oxycodone volume purchased by other chain pharmacies in the Sanford, Florida area. In close proximity to CVS 219 stand two pharmacies – Walgreens #6970, located at 3803 S. Orlando Drive, Sanford, Florida, and Wal-Mart Pharmacy #10-0857, located at 3653 Orlando drive, Sanford, Florida. Walgreens #6970 purchased 176,500 dosage units of oxycodone in 2011. Wal-Mart Pharmacy #10-0857 purchased 30,500 dosage units of oxycodone in 2011. Walgreens and Wal-Mart are each located within one (1) mile of CVS 219. Attachment 23. Additionally, in close proximity to CVS 5195 stands a Publix Pharmacy #0641, located at 5240 West State Road 46, Sanford, Florida 32771. The Publix Pharmacy, as compared to CVS 5195, only purchased 25,700 units of oxycodone in 2011. The two pharmacies are located within two (2) miles of one another. Attachment 24.

52. Although CVS 219's and CVS 5195's purchases of oxycodone decreased between October 2011 and December 2011, *see* Attachments 13 and 14, their monthly purchases of oxycodone remained higher than that of the average Florida pharmacy. Attachment 14.

Failure to Fulfill Their Corresponding Responsibility:

53. From at least 2008 to 2011, CVS 219 and CVS 5195 dispensed controlled substances based upon illegal prescriptions issued by practitioners working at pill mills. DEA and the State of Florida have taken criminal, civil or administrative action against at least twenty practitioners, listed above, whose customers fill their controlled substance prescriptions at CVS 219 and CVS 5195.

54. Employees at both CVS 219 and CVS 5195 filled prescriptions for controlled substances even when they knew or should have known that a large number of the prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. These employees ignored many typical red flags of controlled substance diversion, such as: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; and (e) customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician. The employees who consistently ignored the red flags of controlled substance diversion are still working at CVS 219 and CVS 5195, despite the fact that these individuals continued to fill prescriptions for controlled substances when they knew, or should have known, that a large number of these prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.
55. CVS's November 2011 decision that it would no longer fill Schedule II narcotic prescriptions for twenty-two Florida practitioners, *see supra* ¶ 45, was not a proactive measure taken by CVS/Caremark, Inc. after making an independent determination that the twenty-two practitioners at issue may be issuing invalid prescriptions. Rather, it was simply a reaction to heightened scrutiny by DEA, and one made only after DEA requested dispensing information on these very same practitioners.

Failure to Follow CVS/Caremark, Inc. Policies:

56. The implementation of CVS/Caremark, Inc.'s revised controlled substance dispensing guidelines in January 2012 did not ensure that CVS 219 and CVS 5195 would not continue to dispense controlled substances based on prescriptions that were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. As an initial matter, many of the guidelines listed in the revised guidelines of January 2012 were simply a reiteration of the guidelines listed in CVS/Caremark, Inc.'s previous policies and trainings. Moreover, the AIW interviews conducted with employees at CVS 219 and CVS 5195 showed that the pharmacies were dispensing controlled substances even with the existence of the "warning signs" listed in the company's previous controlled substance dispensing guidelines and trainings. Because CVS 219 and CVS 5195 failed to follow CVS Caremark, Inc.'s previous controlled substance dispensing guidelines in any meaningful way, DEA had no reason to believe that the implementation of revised controlled substance dispensing guidelines would do anything to change the practices employed at CVS 219 and CVS 5195.

DEA Issues Immediate Suspension Orders for CVS 219 and CVS 5195

57. Through my training and experience as both a law enforcement officer and as a licensed pharmacist, I believe that the CVS 219's and CVS 5195's DEA registration to handle and distribute any type of controlled substance poses an imminent danger to the public health and safety. I participated in the decision-making process leading up to the issuance of the ISOs. The information in all the foregoing paragraphs informed

my decision to recommend to the Administrator that ISOs were the appropriate course of action against CVS 219 and CVS 5195.

58. DEA has scheduled an administrative hearing in the CVS 219 matter for April 3, 2012 and in the CVS 5195 matter for April 10, 2012. Absent any request for delay by CVS 219 or CVS 5195 and assuming that the Court does not enjoin the ISOs, DEA expects to conclude agency proceedings by August.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: 2/24/12



JOSEPH T. RANNAZZISI